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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,329

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,329	Applicant(s) XIAN ET AL.	
	Examiner Betty Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2,4-30 and 55 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2,4-30 and 55 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 16 November 2011 in which the previous rejections were traversed.

Applicant's arguments have been thoroughly reviewed but are not found sufficient to overcome the previous rejections.

The previous rejections in the Office Action dated 16 June 2011 are maintained.

Claims 1-2, 4-30 and 55 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4-15, 17-24, 30 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (2003/0235825 filed 21 June 2002) in view of He et al (U.S. Patent No. 7,390,463, filed 24 May 2002).

Regarding Claims 1 and 55, Shea teaches device comprising a substrate (110) having a planer surface and a plurality of microarray areas (11/12) and wherein the substrate comprises an enclosure (3) attached to the substrate (Fig. 4, ¶ 90). Shea teaches the device further comprising a cover having a supporting structure (i.e. snap-fit structure, Fig. 10A) projecting from the cover wherein the supporting structure defines

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the reaction space (§ 58, 92-93). Shea further teaches the device wherein each assay area (11/12) has an access port (7) for fluid delivery and removal (§ 92) but is silent regarding the port projecting into the reaction spaces.

However, fluidic access ports projecting into reaction spaces were known in the art at the time the invention was made as taught by He who teaches each reaction space having a project for fluid delivery and removal wherein the projections “reduce the volume of reagents required to perform an assay, localize the use of reagent solution directly on the biological materials, and stimulate microfluidic flow.”(paragraph spanning columns 7-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the projections of He to the fluidic access ports of Shea. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teaching of He. The artisan would have been further motivated to do based on the desired fluidics of Shea (§ 92) and for the benefit of reduced reagent volume, localized reagent solution directly on the biological materials, and stimulated microfluidic flow”(He, paragraph spanning columns 7-8).

Regarding Claim 2, Shea teaches microarray chip is a slide (§ 53).

Regarding Claim 4, Shea defines the array sections (11/12) formed by array element (3) wherein the array areas have a preferred thickness of 0.1-2mm (§ 75). And He teaches an enclosure area of 0.5 mm (Column 8, lines 3-5).

Regarding Claim 5, Shea teaches a square or rectangular enclosure (Fig. 4, ¶ 75).

Regarding Claim 6, Shea teaches the cover comprises access ports for fluidic delivery (¶ 92) and He teaches the projections for fluidic delivery (Column 3, lines 1-19).

Regarding Claim 7, Shea teaches that each assay section has at least one access port (¶ 92) and illustrates the device having two assay sections four access ports (Fig. 4) which is within the claimed range of 1 to 2,500.

Regarding Claim 8, Shea teaches that each assay section has two access ports (Fig. 4) and He teaches similar device wherein the two access ports are provided in each projection (Fig. 3-4) thereby providing a number of access ports that differs from the number of projections.

Regarding Claim 9, Shea teaches circular/oval access ports (Fig. 4-5) and He teaches circular access ports (Fig. 6).

Regarding Claim 10, Shea is silent regarding the diameter of the access holes however, He teaches diameters of 0.5-0.55mm (Column 5, lines 50-54) which is within the claimed range of 0.01-100mm.

Regarding Claim 11, Shea teaches the device having two assay sections (Fig. 4 and ¶ 92) which is within the claimed range of 2 to 2,500.

Regarding Claim 12, Shea teaches that each assay section has two access ports (Fig. 4) and He teaches similar device wherein the two access ports are provided in each projection (Fig. 3-4) thereby providing a number of access ports that differs from the number of projections.

Regarding Claim 13, Shea is silent regarding projections, but He teaches the similar device wherein the projections and microarray areas have the same shape (Fig. 6).

Regarding Claim 14, Shea defines the array sections (11/12) formed by array element (3) wherein the array areas have a preferred thickness of 0.1-2mm (§ 75). He teaches the projections provide a gap within the array area so as to minimize reagent volumes and maximize mixing (Column 3, lines 1-19).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the array sections of Shea with the fluid delivery projections of He and to provide the projections with a length that minimized reagent volume and maximizes reagent mixing as taught by He. One of ordinary skill, using the guidance of He, would have derived projections within the claimed range based on the array thickness of 0.1-2mm as taught by Shea.

Regarding Claim 15, Shea teaches circular/oval access ports (Fig. 4-5) and He teaches circular access ports (Fig. 6).

Regarding Claim 17, Shea defines the array sections (11/12) formed by array element (3) wherein the array areas have a preferred thickness of 0.1-2mm (§ 75). And He teaches an enclosure area of 0.5 mm (Column 8, lines 3-5).

Regarding Claim 18, Shea teaches the array sections have a volume of 10-1000 μl (§ 92) and He teaches a volume of 500 μl (Column 8, lines 3-5) thereby teaches volumes within the claimed range.

Regarding Claim 19, Shea teaches the device comprising glass, silicon, and plastics (§ 53) and He teaches glass, polymers and metals (Column 5, lines 39-41).

Regarding Claims 20-22, Shea teaches the cover is made from glass or plastic e.g. polycarbonate (§ 84) wherein the components are molded (§ 90). He also teaches polymeric material and injection molding (Column 10, lines 52-54).

Regarding Claims 23-24, Shea teaches the device wherein the cover comprises glass (§ 84). Shea is silent regarding fabrication of the glass. However, the courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Therefore, absent evidence to the contrary, the instantly claimed glass cover does not distinguish over the prior art of Shea.

Regarding Claim 30, Shea teaches probes immobilized in the microarray area (§ 68-70) and He teaches probes immobilized in the microarray area (Column 5, lines 64-Column 6, line 3).

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4. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (2003/0235825 filed 21 June 2002) in view of He et al (U.S. Patent No. 7,390,463, filed 24 May 2002) as applied to Claim 1 above and further in view of Webb et (U.S. Patent No. 7,332,3238, filed 6 September 2002).

Regarding Claims 16-18, Shea defines the array sections (11/12) formed by array element (3) wherein the array areas have a preferred thickness of 0.1-2mm (§ 75) and a volume of 10-1000 μ l (§ 92). He teaches a similar enclosure having an area of 0.5 mm (Column 8, lines 3-5) and volume of 500 μ l (Column 8, lines 3-5)

He is silent regarding the area of the projections. However, Webb teaches a very similar device comprising a cover having fluidic projections into the reaction spaces wherein the surface of the projections has an area of 10-250 microns (Column 14, lines 63-65) wherein a gap between the projections and microarray is 175 μ l (Example 2, Column 20, lines 4-10) and wherein the reaction volume is 9 μ l (Example 2, Table 4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to that given the similarity of the He and Webb device, that the surface area of He's projections would have been within the claimed range of 0.01-600 mm².

5. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (2003/0235825 filed 21 June 2002) in view of He et al (U.S. Patent No.

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7,390,463, filed 24 May 2002) as applied to Claim 1 above and further in view of MacBeath (U.S. Patent No. 7,063,979, filed 13 June 2002).

Regarding Claim 25-29, Shea teaches the assay area element (3) forming the enclosure is elastomeric (§ 95) but does not specifically teach rubber and double or single coated tape.

However, silicone/rubber chambers for forming reaction chambers were known to use adhesive tape (e.g. double-sided and/or compressable material treated for adhesion) for forming water-tight seals as taught by MacBeath (Column 8, lines 55-67 and Column 17, lines 18-50). MacBeath teaches the device wherein the treated gaskets provide the chambers with a watertight seal between the gasket and the microarray thereby preventing cross-contamination between the wells/chambers (Column 6, line 53-Column 7, line 20).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the elastomeric enclosure of Shea by adding the double-sided tape adhesive of MacBeath. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of providing a water-tight seal between the wells/chamber thereby preventing cross-contamination as taught by MacBeath (Column 6, lines 53-67).

Claims 26 and 28 define methods for making the enclosure by stamping. However, as noted above, the courts have stated that a process for making a device does not define the device over a prior art device made by another method. Therefore the instantly claimed stamping does not patentably distinguish the device.

Response to Arguments

6. Applicant argues that the reaction space of Shea is formed between the substrate (110) and recessed portion (9) but does not teach the reaction space between the microarray chip and projection as instantly claimed.

Applicant argues that He does not cure the deficiencies of Shea because the reference does not teach an enclosure attached to the microarray chip to form a microarray area.

Applicant further argues that one of ordinary skill would not be motivated to combine the He with that of Shea because doing so would render the Shea device unsatisfactory for its intended purpose.

The arguments have been considered but are not deemed sufficient to overcome the rejection. As discussed above, Shea teaches the microarray chip (110), reaction area (11/12), an enclosure (3) and a cover (5) with the supporting structure wherein the enclosure is less than the supporting structure (Fig. 10A). While Shea does not teach that the cover has projections, He teaches the cover and projections wherein the projections function to deliver controlled volumes of reagents to each microarray/reaction area and minimize reagent loss via evaporation (paragraph spanning columns 7-8). Furthermore, both Shea and He teach devices have defined reaction areas, each having a microarray. The devices differ in the structures used for reagent delivery. Shea teaches reagent delivery via ports (7) while He teaches reagent delivery via fluidic channels within the projection. He teaches the advantages of

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delivering the reagents via the projections i.e. to deliver controlled volumes of reagents to each microarray/reaction area and minimize reagent loss via evaporation (paragraph spanning columns 7-8). It is unclear to the examiner how using the projects of He would not render the device of Shea unsatisfactory as asserted by Applicant. In contrast, it appears that providing the device of Shea with the projections of He would improve the device for its intended purpose i.e. fluidic assay.

It is maintained that the combined teaching of Shea and He teach all the elements of the invention as claimed.

Applicant argues that Webb does not cure the deficiencies of Shea and He. The argument is not persuasive because Shea and He are not deemed deficient.

Applicant further argues that MacBeath does not cure the deficiencies of Shea and He. The argument is not persuasive because Shea and He are not deemed deficient.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Forman whose telephone number is (571)272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Betty Forman
Primary Examiner
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